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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,850

12/08/2006

William Brown

101259-1P US

1336

22466

7590

07/03/2008

ASTRA ZENECA PHARMACEUTICALS LP  
GLOBAL INTELLECTUAL PROPERTY  
1800 CONCORD PIKE  
WILMINGTON, DE 19850-5437

EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

07/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/596,850	<b>Applicant(s)</b> BROWN ET AL.	
	<b>Examiner</b> Taofiq A. Solola	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-5,8-13 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-5,8,17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>na</u> .  | 6) <input type="checkbox"/> Other: _____                          |

Claims 1-5, 8-13, 17-19 are pending in this application.

Claims 9-13, 19 are drawn to non-elected invention.

Claims 6-7, 14-16 are deleted.

***Priority Claim***

The instant application is filed more than 30 months from the filing date of the foreign priority document and more than 18 months from the filing date of the PCT priority document. Therefore, the claimed priority is not valid.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al., WO 2004/041802 A1, in view of Wei et al., J. Med. Chem. (2000) Vol. 43, pp. 3895-3905.

Applicant claims compounds of formula I and composition thereof useful for the treatment of pain, or GI disorders. In the compounds, R2 is optionally substituted alkyl, alkenyl, cycloalkyl, etc. R1 is H or optionally substituted alkyl, and R3 is alkyl or cycloalkyl.

**Determination of the scope and content of the prior art (MPEP 2141.01)**

Brown et al., teach similar compounds and composition thereof useful for the treatment of pain, or GI disorders. In preferred embodiment, R2 (instant R1) is H or substituted alkyl; R1 (instant R2) is H or alkyl; and R3 is alkyl or cycloalkyl. See the abstract, page 8, line 20 and page 9, first paragraph.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Brown et al., is that Applicant's compounds have piperidine and exocyclic carbon-carbon double bond instead of piperazine and exocyclic carbon-carbon single bond by Brown et al.

Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)

However, Wei et al., teach replacement of piperazine and the exocyclic carbon-carbon single bond with piperidine and exocyclic carbon-carbon double bond would produce compounds with increased binding affinity. See page 3896, col. 1, lines 1-11.

When R<sub>2</sub> is H in the prior art, the compounds are 2° amine while the instant compounds are 3° amines. However, 2° and 3° amines are obvious variants, *Ex parte Bluestone*, 135 USPQ 199 (1961).

Therefore, the instant invention is prima facie obvious from the teachings of Brown et al., and Wei et al. One of ordinary skill in the art would have known to replace piperazine and the exocyclic carbon-carbon single bond with piperidine and exocyclic carbon-carbon double, and claim 3° amines instead of 2° amines at the time the invention was made. The motivation is from the teaching of Wei et al., that such replacement would produce compounds with increased binding affinity and from knowing that 2° and 3° amines are obvious variants.

Alternatively, given the teachings of the prior arts, it would have been obvious to try replacement of piperazine and the exocyclic carbon-carbon single bond with piperidine and exocyclic carbon-carbon double bond, and claim 3° amines instead of 2° amines at the time the invention was made.

When there is motivation

to solve a problem and there are a finite number of identified,  
predictable solutions, a person of ordinary skill has good reason to

pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 USC] 103.

*KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct 1727,-----, 82 USPQ2d 1385, 1397 (2007).

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, Art Unit 1625

June 26, 2008

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